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Dockets Management Branch (HFA-305)
Food and Drug Administration, Rm. 1-23
12420 Parklawn Drive
Rockville, Maryland 20857

**RE: Docket No. 98N-0148, 63 Fed. Reg. 13258, International Drug
Scheduling; Convention on Psychotropic Substances; Dihydroetorphine;
Ephedrine; Remifentaryl; Isomers of Psychotropic Substances**

Dear Sir or Madam:

On March 18, 1998, FDA published the above-referenced notice requesting comments concerning abuse potential, actual abuse, medical usefulness, and trafficking of dihydroetorphine, ephedrine, and remifentaryl. The notice stated this information would be considered in preparing a U.S. response to a World Health Organization (WHO) notification.

Whitehall-Robins Healthcare manufactures Primatene Tablets, an OTC bronchodilator drug product that contains ephedrine. Whitehall-Robins is, therefore, an interested party to this action. As such we are greatly concerned that the actions of the World Health Organization may adversely impact the recognized US market status of a product containing a safe and effective ingredient.

Whitehall-Robins is herewith submitting for your consideration a document that addresses the issues surrounding alleged abuse and misuse of ephedrine in the context of the consumer's need for an over-the-counter asthma product. We call to your attention that there are inherent differences between products that are lawfully labeled and marketed for use as bronchodilators and those which are improperly and illegally promoted for other uses.

98N-0148

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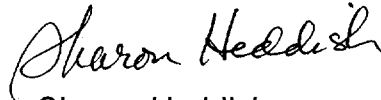
We strongly urge FDA to both file comment, and attend the scheduled meeting of the World Health Organization. FDA in its comments must reinforce its recognition of ephedrine's safety as a nonprescription medicine.

We ask that FDA carefully consider the comments provided in developing both its position, and its specific comment to the World Health Organization Expert Committee on Psychotropic Substances.

If you have any questions or comments, please do not hesitate to contact the undersigned at (973) 660-5753 or Mr. Vin Milano at (973) 660-6160.

Sincerely,

WHITEHALL ROBINS HEALTHCARE

A handwritten signature in black ink, reading "Sharon Heddish". The signature is fluid and cursive, with the first name "Sharon" being more prominent than the last name "Heddish".

Sharon Heddish
Vice President,
Regulatory Affairs Worldwide

**Docket No. 98N-0148, 63 Fed. Reg. 13258,
International Drug Scheduling; Convention on Psychotropic Substances;
Dihydroetorphine; Ephedrine; Remifentanyl; Isomers of Psychotropic Substances**

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Docket 98N-0148

**International Drug Scheduling;
Convention on Psychotropic Substances**

Submission of Whitehall Robins Healthcare 4/17/98 to FDA for W.H.O.

Thirty-First Expert Committee on Drug Dependence

June 23-26, 1998

**EPHEDRINE IS A SAFE AND EFFECTIVE INGREDIENT
FOR USE AS A NONPRESCRIPTION BRONCHODILATOR**

Executive Summary

This document is submitted by Whitehall-Robins Healthcare to support continued recognition that ephedrine is a safe and effective nonprescription bronchodilator in the United States. The company's Primatene Tablet products, which contain ephedrine, have provided safe and effective relief to mild asthmatics for more than forty years.

The safety and effectiveness of ephedrine for its intended use are well established, were carefully considered by U.S. FDA during its monograph process, and, indeed, are unchallenged today.

FDA has long recognized and, with the support of its advisory committees composed of acknowledged experts in the field, continues to recognize that persons suffering from mild physician-diagnosed asthma should be able to self-treat their symptoms with nonprescription medications. Primatene Tablets are the predominant OTC tablets available to meet this need.

W.H.O. is considering changing the schedule status of ephedrine because of concerns with ephedrine abuse. However, the abusers are not asthmatics and the abused products are not lawfully marketed bronchodilators such as Primatene Tablets. It would be arbitrary and unfair for W.H.O. to address an altogether distinct abuse issue by removing Primatene and other mainstream asthma medicines from the market. Legitimate

manufacturers of ephedrine-containing bronchodilators have taken appropriate steps to deter abuse and diversion by strict control of raw materials, GMP manufacture, blister packaging and inventory control in accordance with U.S. Federal and State law. The proposed limitation on distribution of these products is an inappropriate regulatory response to a problem that is essentially one of misbranding and illegal promotion, rather than pharmacological safety.

I. Introduction

This document is submitted by Whitehall-Robins Healthcare, a division of American Home Products Corporation, producing over-the-counter (OTC) for the U.S. market. This document is in three sections. Following this introduction, the second part of this document reviews the appropriateness and utility of ephedrine for use as a bronchodilator in mild asthma and the third part addresses regulatory agency concerns with the abuse of ephedrine products.

Whitehall-Robins has marketed over-the-counter asthma medications in the U.S. for more than 40 years. The company currently markets one asthma medication in tablet form: Primatene,[®] which is a combination of ephedrine 12.5mg and guaifenesin USP 200mg per tablet, for the relief of asthma symptoms and chest congestion.

Wyeth-Ayerst, another division of American Home Products Corporation, markets one ephedrine-containing product: Davenol Linctus. This product contains carbinoxamine maleate 2mg, ephedrine hydrochloride 7mg and pholcodine 4mg per 5ml. It is manufactured in Pakistan and is currently sold in Pakistan, Mauritius and Kenya. It is indicated for temporary relief of cough associated with minor throat and bronchial irritation.

II. Ephedrine is an appropriate and useful OTC anti-asthma medication

A. FDA has consistently recognized ephedrine as a safe and effective OTC product

The continued OTC availability of ephedrine is fully supported by the fact that FDA (the agency) carefully considered ephedrine in the monograph process for bronchodilator products and concluded that it is generally recognized as safe and effective (GRAS/E) for use as a nonprescription anti-asthma medication. The OTC status of ephedrine is the result of over a decade of careful review of scientific data and public comments. As illustrated below, the FDA's conclusion throughout the monograph process has been clear and consistent: ephedrine is a safe and effective ingredient for OTC use.

Under the US monograph review system, many OTC drugs are generally recognized among qualified experts as safe and effective for use and as not misbranded by panel review. These panels of qualified experts evaluate the safety and effectiveness of OTC drugs, review labeling, and advise on the promulgation of Monographs establishing conditions under which OTC drugs are generally recognized as safe and effective and not misbranded. A single advisory review panel is established for each designated category of OTC drug. This monograph may include conditions relating to active ingredients, labeling indications, warnings and adequate

directions for use, and any other conditions necessary and appropriate for the safety and effectiveness of drugs covered. The panel's conclusions are published in the Federal Register to obtain full public comment at several review stages preceding promulgation into law.

In the FDA proposed monograph for OTC cold, cough, allergy, bronchodilator, and anti-asthmatic drug products, an independent advisory review panel (the Panel) evaluated the safety and effectiveness data on ephedrine and concluded that "ephedrine preparations are safe and effective for OTC use as bronchodilators."¹ The Commissioner made an initial determination to accept the Panel's recommendation.²

After considering extensive comments and independent evaluation of the Panel's report, FDA published a tentative final monograph.³ In the tentative final monograph, the agency agreed with the Panel that single-ingredient ephedrine preparations are generally recognized as safe and effective.⁴

Four years later, FDA published a final monograph.⁵ After further review of additional data and comments submitted in response to the tentative final monograph, the agency reaffirmed its earlier decision that ephedrine is generally recognized as safe and effective (GRAS/E).⁶ The agency explicitly stated that ephedrine is an "essential medication"⁷ and

that, with appropriate labeling, it can be safely and effectively used as an OTC bronchodilator.⁸ This conclusion is embodied in FDA's final regulation⁹ listing ephedrine as a permissible nonprescription bronchodilator active ingredient.

In its most recent action regarding ephedrine as an OTC bronchodilator, FDA issued a tentative final monograph for combination products.¹⁰ In this notice of proposed rulemaking, the agency adopted the Panel's recommendation that bronchodilator and expectorant combination products (such as ephedrine and guaifenesin formulations) are generally recognized as safe and effective provided they are labeled for cough associated with asthma.¹¹ The agency explained that guaifenesin would be included as a monograph ingredient in the final monograph for OTC expectorant drug products.¹² Guaifenesin's monograph status has subsequently been made final.¹³

B. Ephedrine's OTC availability is essential to asthma sufferers

Regulatory agencies should be especially reluctant to disturb the schedule status of ephedrine because it has long been recognized that the OTC availability of anti-asthma medication has been invaluable to asthma sufferers. The Panel in the proposed monograph determined that despite

possible risks associated with the self-diagnosis and self-treatment of asthma, "it is reasonable to have bronchodilators available on a nonprescription basis" because asthma is a common disease and bronchodilators can provide immediate relief without the possible delays of obtaining a physician's prescription.¹⁴ Recognizing the "consumer's prerogative for self-medication",¹⁵ the Panel concluded that bronchodilators are safe and effective for OTC use when properly labeled and used as directed.¹⁶

FDA confirmed this recommendation in the final monograph. Rejecting comments that objected to the OTC marketing of anti-asthma medicines, the agency noted that continued OTC availability of bronchodilators has clearly aided asthmatics and is supported by years of safe and effective use:

OTC availability of bronchodilator drug products provides asthmatics ready access to this essential medication without the need for additional visits to a physician's office or to a hospital emergency room. This availability especially benefits those asthmatics whose attacks are triggered by common environmental factors (e.g., primarily by exertion, anxiety, exposure to cold, etc.) when immediate use may be essential. In addition, physician-diagnosed asthmatics who do not have easy access to medical care will continue to benefit from OTC use.¹⁷

Like the Panel, FDA concluded that any risks due to self-diagnosis

and self-medication can be adequately addressed by appropriate labeling.¹⁸ FDA and its outside advisers continue to recognize the appropriateness of OTC asthma treatment. FDA has established advisory committees to provide independent, professional expertise and technical assistance on the development, safety and effectiveness, and regulation of drug products. Each committee consists of experts with recognized expertise and judgment in a specific field. Members have the training and experience necessary to evaluate information objectively and to interpret its significance. They provide independent expert advice, helping the FDA make sound decisions about new drugs, biologics, medical devices, and other public health issues. Committee members are scientific experts such as physician-researchers and statisticians, as well as representatives of the public, including patients. These persons are not regular employees of FDA, but are considered "special government employees" for the days they participate as members of a panel. The committees are advisory -- they provide their expertise and recommendations -- but FDA using the panel's input makes final decisions.

At the November 14, 1994, Joint Meeting of the Pulmonary-Allergy and Nonprescription Drugs Advisory Committees, for instance, the group concluded that OTC availability of anti-asthma medication is important to a defined group of asthma sufferers. In particular, those suffering from mild

asthma and experiencing infrequent attacks benefit greatly from OTC availability.¹⁹

The view has been expressed that if ephedrine were removed from the OTC market, asthmatics would not be affected because other OTC anti-asthma medications (such as inhalers) will still be available. This is not a valid assessment for two reasons. First, each product should be judged on its own merits, not in comparison with other products. Additionally, and more importantly, a significant proportion of tablet users do not consider metered dose inhalers to be an acceptable alternative.

In a recent submission,²⁰ Whitehall-Robins Healthcare established the fact that there exists a recognizable population of physician-diagnosed asthmatics for whom OTC bronchodilators are an appropriate treatment. A more recent consumer survey²¹ was undertaken to further characterize the consumers who use ephedrine combination tablets. These asthma sufferers rely primarily on OTC medications (64%). Thirty-six percent (36%) of combination tablet users rely exclusively on that form. Another 36% use OTC tablets and a prescription medication. For these asthma sufferers, removal of Primatene Tablets means there will be no over-the-counter medication for their asthma symptoms.

C. There is no compelling reason to change ephedrine's regulatory status

As clearly shown by the U.S. FDA monograph process for bronchodilator products, conclusions in monographs represent well-considered agency determinations based on evaluation of an independent advisory review panel report and submitted public comments. The monograph status should not, therefore, be reopened without compelling reasons. Such reasons do not seem to be present here.

The safety and effectiveness of ephedrine for its intended use is not being challenged. Government agencies cite abuse of ephedrine-containing products as the reason requiring revocation of ephedrine's current status. The only ephedrine products of concern, however, are those that are promoted unlawfully for use as weight-loss aids and stimulants, not those such as Primatene Tablets that are lawfully promoted for the symptomatic treatment of doctor-diagnosed mild asthma -- the only approved labeling indication included in the final monograph. The abuse of illegal products is not a valid reason for discontinuing the OTC availability of legitimate ephedrine products that have provided and continue to provide asthma sufferers with essential safe and effective relief without the attendant delay of obtaining a physician's prescription.

Most importantly, the scientific and medical data support FDA's

earlier conclusion that ephedrine is a safe and effective ingredient for use as an OTC bronchodilator. The Panel's report in the proposed monograph for bronchodilators cited four studies as evidence of ephedrine's effectiveness.²² Since those four studies were conducted, at least three double-blind, placebo-controlled clinical trials have confirmed that ephedrine is effective in the symptomatic treatment of asthma.²³

Ephedrine's safety profile has also been verified by additional clinical data. In the proposed monograph, the Panel cited two studies demonstrating that ephedrine has no significant effect on either heart rate or blood pressure.²⁴ Ephedrine's tolerability has subsequently been confirmed in a six-month, randomized, double-blind parallel group study of patients with reversible asthma.²⁵ During the six-month study period, the ephedrine treatment group reported no significant effects on heart rate, systolic blood pressure, or diastolic blood pressure.

The appropriateness of ephedrine's current regulatory status as a safe bronchodilator has also been illustrated in a review study of the toxicity of over-the-counter stimulants.²⁶ This review of the medical literature found few reported cases of ephedrine-associated adverse events.

Discontinuing the current status of ephedrine should not be based merely on the fact that ephedrine is an "older drug" and that "newer drugs"

with additional advantages are currently available. Many valuable older drugs, such as aspirin and digitalis, have remained on the market despite the presence of newer drugs. This is in accordance with the longstanding policy of the agency that a safe and effective drug should remain on the market, whether it is old or new. As the agency stated in the final monograph for combination products, "[g]eneral recognition of safety and effectiveness is not based on comparison."²⁷ FDA evaluates "ingredients individually on whether they can be generally recognized as safe and effective for OTC use."²⁸ The agency has judged ephedrine to be such an ingredient.

III. W.H.O. should not make F.D.A. remove lawfully marketed ephedrine products because of concerns about abuse of illegal ephedrine products

A. "Mainstream" ephedrine products such as Primatene Tablets are not abused

For decades, Primatene Tablets and other mainstream ephedrine products have been produced, packaged, and promoted exclusively for their approved use as bronchodilators for the treatment of asthma. Recently, however, a small number of manufacturers have created a market for ephedrine products that are labeled as bronchodilators under the monograph but are illegally promoted for other, unapproved uses.

We agree that these illegal promotional practices must be curtailed.

However, it appears to be an unnecessary and misdirected regulatory action to ban lawful ephedrine products that are not abused in order to eliminate illegal ephedrine products that are abused.²⁹

Unlike Primatene Tablets, which are properly promoted, these other ephedrine products are positioned in the marketplace so as to invite ephedrine abuse. Product names such as "Mini Thins", "Buzzy Gum," "Heads Up," "Pink Hearts," "ThinEdrine," and "White Cross" encourage consumers to purchase these products for unapproved uses -- namely, for use as stimulants, appetite suppressants, and muscle performance enhancers.

Finally, atypical chains of distribution such as sales at rest stop stores, at candy counters in convenience stores, and through mail-order advertisements in magazines further facilitate the illegal promotion and abuse of these products. (See Attachment 1, infra.) Nielsen Procision Sales Data Corporation,³⁰ the most highly rated sales tracking service in the United States, reported no sales of these products in drug stores or mass merchandise outlets in a three year period. Thus, no sales can be documented in the usual channels of distribution that would be appropriate for products objectively intended by their vendors for anti-asthmatic use. (See Attachment 2, infra.) Unlike these illegal ephedrine products,

Primatene Tablets are not sold at candy counters, nor are they available to consumers via mail order.

One measure of incidence of ephedrine abuse is provided by data accumulated by the Drug Abuse Warning Network (DAWN). It should be recalled that these data include emergency room visits associated with the ingestion of improperly promoted ephedrine products as well as misuse of properly labelled products. According to 1992 Drug Abuse Warning Network (DAWN) data,³¹ ephedrine ranks 69th in drugs associated with emergency room visits. In 1992, ephedrine-related abuse comprised only 0.21% of total drug abuse emergency room episodes. In the 1996 DAWN Summary Report on annual trends in prescription and over-the-counter drug-related episodes, no specific mention is made of problems relating to ephedrine abuse.

The small number of DAWN reports on misuse/abuse of ephedrine is even more striking when compared to Whitehall-Robins internal database of adverse event reports for Primatene Tablets. Since 1980, only 369 adverse event reports have been received for all formulations of Primatene that have included ephedrine. Four previous formulations, which include other active pharmaceutical agents, are no longer marketed. Of these 369 reports, 150 were related to insufficient drug effect, rather than specific

adverse events. With sales of over 1.2 billion tablets, this is an approximate incidence of only 1 adverse event per 3 million tablets. Of these adverse events, there have only been three serious reports and no deaths. It would be unreasonable for the agency to rescind the OTC status of a product that is efficacious and safe in order to solve a problem that has resulted solely from the illegal promotion of a handful of other products.

B. Abuse of illegal products is not an appropriate rationale for banning legitimate OTC bronchodilators

If required to support a proposed ban on the nonprescription availability of all ephedrine-containing products, FDA could presumably cite the regulatory standard of safety for OTC products.³² Pursuant to this regulation, the standard of safety for OTC drug products includes a "low potential for harm which may result from abuse under conditions of widespread availability." Primatene Tablets, and other lawfully marketed ephedrine bronchodilators, satisfy this standard of safety.

To maintain otherwise is to incorrectly interpret this standard as requiring a "low potential for harm" even for ephedrine products that are not lawfully marketed under the monograph. The regulatory questions must be the potential for abuse of lawful monograph products, not products that are illegal wholly apart from the monographs.

Illegal versions of many legitimate OTC monograph products presumably can be abused by those set on a self-destructive course, encouraged by unscrupulous marketers. This appears to be an insufficient reason to ban the legal products rather than controlling the illegal ones. It also seems to try to enforce a "zero-risk" standard that is without basis in the law and is, in any event, unachievable in fact.

As both the Panel and the FDA clearly understood during the monograph process, such a "zero-risk" safety standard would deprive the public of valuable medicines since "abuse of OTC products can be expected to occur."³³ In particular, the Panel and agency were aware that sympathomimetics such as ephedrine can be subject to abuse.³⁴ Nonetheless, ephedrine was classified as a monograph ingredient because "drugs having documented effectiveness, therapeutic utility, and safety when used prudently for self-diagnosable conditions in accordance with label instructions represent a valuable, national public health resource."³⁵

C. **A complete ban on ephedrine is unnecessary because enforcement action can be taken directly against the illegal ephedrine products**

Consideration of a rulemaking to remove lawfully-marketed ephedrine from the OTC market is especially unwarranted because the FDA can take enforcement action directly against the illegal products.

The ephedrine products that trouble FDA and other agencies are those being unlawfully promoted for uses other than bronchodilation. In determining a product's intended use, FDA may consider, not only labeling claims, but also all "advertising matter" and "circumstances surrounding the distribution of the article" to establish the objective intent of the vendor.³⁶ Available evidence conclusively indicates that these abused products are being marketed not as bronchodilators, but as weight-loss aids and stimulants (see Attachment 1, infra). The advertising claims promoting them, such as "Nature's Ultimate Energy Source," "Stimulant-Diet Aids," "Increase Endurance by Over 200% During Workouts," "Increase Concentration," "Increase Strength from Day One," and "Triple Training Intensity" (see Attachment 1, infra) encourage consumers to abuse these products. Because of these misleading advertising claims, many unsuspecting consumers (especially athletes and diet conscious teenagers) believe that they can safely use these products for purposes other than the treatment of asthma. Given such intended uses, these products are "misbranded" under section 502(f)(1) of the Federal Food, Drug, and Cosmetic Act (the Act). In particular, they are misbranded because they fail to bear "adequate directions for use" since their product labels do not state the purpose or condition for which they are intended.³⁷ If, however,

the manufacturers of these misbranded ephedrine products were to comply with section 502(f)(1) of the Act and provide adequate directions for use, the products would then be unapproved new drugs that would be subject to enforcement action under section 505 -- the so-called "squeeze play".³⁸

The fact that these products bear labeling under the bronchodilator monograph is irrelevant because their vendors harbor other intended uses for them. Thus, FDA can take action against these misbranded products and their marketers through one of a number of remedies, including product seizure, injunction, and criminal prosecution. In fact, enforcement action would not be burdensome to the agency. In fact, enforcement action would not be burdensome to the agency because only a small number of manufacturers are promoting ephedrine products illegally, and the evidence of unlawful intent is so clear.

In addition to the remedies available to the FDA, the Federal Trade Commission (FTC) and the Drug Enforcement Administration (DEA) have the authority to curtail abuse of these products. Indeed, it may be more appropriate for DEA to address this issue. DEA has already taken a first step toward controlling ephedrine abuse. Under the regulations³⁹ for implementing the Domestic Chemical Diversion Control Act of 1993, DEA imposes strict record-keeping requirements and distribution controls on

single-ingredient ephedrine products containing therapeutically insignificant quantities of another active ingredient in order to prevent diversion to illegal substance production laboratories.^{40,41} Lawfully marketed ephedrine-containing combination products (such as Primatene Tablets) would be exempted from these controls.⁴²

Pursuant to the provisions of the Chemical Diversion and Trafficking Act of 1988, the Domestic Chemical Diversion Control Act of 1993 and, most recently, the Comprehensive Methamphetamine Control Act of 1996 ("CMCA"), the United States Drug Enforcement Administration ("DEA") has been given broad statutory powers to prevent illicit diversion of a number of precursor chemicals, including ephedrine. These laws require that manufacturers and distributors of the regulated products be licensed and make regular reports about their activities. Additionally, the CMCA imposed significant restrictions on the retail sale of these products, including the requirement that they be sold in blister packages of limited quantities with significant limitations on transaction size.

These regulations further curtail abuse of illegal ephedrine products because sales at rest stops and convenience stores are more difficult. The regulations require distributors and retailers of single-ingredient ephedrine products to register annually with the DEA.⁴³ Retailers are also required to

stock these products behind a counter where only employees have access.⁴⁴

Finally, each regulated entity is required to report any regulated transaction “involving an extraordinary quantity of a listed chemical.”⁴⁵ Legitimate manufacturers of ephedrine-containing bronchodilators have taken appropriate steps to deter abuse and diversion by strict control of raw materials, GMP manufacture, blister packaging and inventory control in accordance with U.S. Federal and State law.

In tandem with DEA's proposed controls on ephedrine distribution, FTC can take enforcement action against the marketing practices that cause ephedrine abuse. The FTC, which has jurisdiction over OTC drug advertising, can act against persons making unsubstantiated advertising claims for the illegal ephedrine products pursuant to section 5 of the Federal Trade Commission Act, 15 U.S.C. §45.⁴⁶

D. Any remaining concerns with lawful ephedrine products can be addressed through a label statement

As discussed above, the data demonstrate that Primatene is not abused. Nonetheless, to the extent that FDA has any concerns with the potential for such abuse, we have voluntarily added the following new warning to our ephedrine products:

Intentional abuse of this product for uses other than those described on this label can be harmful or fatal.

The agency has consistently recognized that the addition of a warning is preferable to removing a product from the market that is safe and effective when used as directed.⁴⁷ Primatene ephedrine-containing products labeling is in compliance with all applicable U.S. regulations for OTC bronchodilator products.

It would be inconsistent with these and other precedents for FDA to remove safe and effective ephedrine-containing products from the market rather than approving an appropriate modification of the label.

Conclusion

Ephedrine is a safe and effective nonprescription bronchodilator. Ephedrine-containing tablets are a well-established and useful nonprescription product. Regulatory agencies should not repeal ephedrine's current schedule status, and thereby take legitimate products such as Primatene Tablets off the market, as a means of addressing the abuse of illegally promoted ephedrine products. Enforcement action against those products is possible under misbranding regulations. To move against illegally promoted products by taking Primatene Tablets off the market is an indirect and unfocussed approach, and one that is not in the best interest of the public.

Attachments

1. Example of Illegal Promotional Materials for Ephedrine-containing products
2. Sales data for OTC Asthma Medications including Primatene Mist and Tablets
3. Methodology for collection of DAWN data
4. Methodology of National Family Opinion Survey

References

1. 41 Fed. Reg. 38312, 38370 (September 9, 1976)
2. Id. at 38312
3. 47 Fed. Reg. 47520 (October 26, 1982)
4. Id. at 47524
5. 51 Fed. Reg. 35326 (October 2, 1986)
6. Id. at 35338
7. Id. at 35327
8. Id. at 35327, 35332
9. 21 C.F.R. § 341.16
10. 53 Fed. Reg. 30522 (August 12, 1988)
11. Id. at 30556
12. Id. at 30523
13. 54 Fed. Reg. 8509 (February 28, 1989); 21 C.F.R. § 341.18
14. 41 Fed. Reg. at 38320

15. Id. at 38323
16. Id. at 38320
17. 51 Fed. Reg. at 35327
18. Id.
19. Transcript of Joint Meeting of the Nonprescription Drugs Advisory Committee and the Pulmonary-Allergy Advisory Committee (November 14, 1994) at 157, 209, 240, 245-249.
20. Docket 94N-10232. October 19, 1994
21. National Family Opinion (NFO) 1995 Survey of Asthma Sufferers Who Use Non-Prescription Ephedrine Combination Tablet Medications. See Attachment 4 for summary of survey methods.
22. 41 Fed. Reg. at 38371, citing Dulfano MJ, Glass P: Evaluation of a new B₂ adrenergic receptor stimulant, terbutaline, in bronchial asthma. II. Oral comparison with ephedrine. Curr Ther Res 15:150-157, 1973; Tashkin DP, Meth R. Simmons DH, Lee EY: Double-blind comparison of acute bronchial and cardiovascular effects of oral terbutaline and ephedrine. Chest 68:155-161, 1975; Bresnick E, Beakey JF, Levinson L, Segal MS: Evaluation of therapeutic substances employed for the relief of bronchospasm. V. Adrenergic agents. J Clin Invest 28:1182-1189, 1949; Cohen BM, Elizabeth NJ:

- Sympathomimetic/xanthine broncholysis in obstructive ventilatory disorders. *Int J Clin Pharmacol Ther Toxicol* 9:6-15, 1974.
23. McLaughlin ET, Bethea LH, Wittig HJ: Comparison of the bronchodilator effect of oral fenoterol and ephedrine in asthmatic children. *Ann Allergy* 49:191-195, 1982; Weinberger M, Bronsky E: Interaction of ephedrine and theophylline. *Clin Pharmacol Ther* 17:585-592, 1975; Pinnaas JL, Thoden WR, Roseberry HR, Schachtel BP: Efficacy of oral theophylline-ephedrine in asthmatic patients. *Clin Pharmacol Ther* 45:169, 1989.
24. 41 Fed. Reg. at 38371, citing Dulfano MJ, Glass P: Evaluation of a new B₂ adrenergic receptor stimulant, terbutaline, in bronchial asthma. II. Oral comparison with ephedrine. *Curr Ther Res* 15:150-157, 1973; Tashkin DP, Meth R, Simmons DH, Lee EY: Double-blind comparison of acute bronchial and cardiovascular effects of oral terbutaline and ephedrine. *Chest* 68:155-161, 1975.
25. Miller J, Wallace D, Grieco MN, Frenkel R, Larsen K: Double-blind trial of oral carbutoleol in bronchial asthma. *Ann Allergy* 39:12-17, 1977.
26. Pentel P: Toxicity of over-the-counter stimulants. *JAMA* 252:1898-1903, 1984.
27. 53 Fed. Reg. at 30526
28. Id.
29. e.g., Motor Vehicle Manufacturers Ass'n, supra, 463 U.S. at 43 (there must be a "rational connection between the facts found and the choice made"), citing

Burlington Truck Lines, Inc. v. United States, 371 U.S. 156, 168 (1962).

30. Nielsen Precision Sales Data: Bronchial Remedies Brand Summary
31. DAWN is a large-scale ongoing drug abuse data collection system maintained by the Department of Health and Human Services. See Attachment 3, infra.
32. 21 C.F.R. § 330.10 (a)(4)(i)
33. 41 Fed. Reg. at 38332
34. *Id.* at 38332
35. *Id.* at 38332 (emphasis added)
36. 21 C.F.R. § 201.128. See also V.E. Irons, Inc. v. United States, 244 F.2d 34, 44 (1st Cir. 1957), cert. denied, 354 U.S. 923 (evidence of "intended uses" goes beyond specific claims made on the label of a product); United States v. Hohensee, 243 F.2d 367, 370 (3rd Cir. 1957), cert. denied, 353 U.S. 976 (same).
37. Alberty Food Products Co. v. United States, 185 F.2d 321, 325-326 (9th Cir. 1950) ("adequate directions for use" requires that the label of a product contain the purpose or condition for which the product is intended); United States v. 38 Dozen Bottles, Etc., 114 F.Supp. 461, 464 (D.Minn. 1953) (same).
38. V.E. Irons, 244 F.2d 34; Hohensee, 243 F.2d 367; Alberty, 185 F.2d 321; 38

Dozen Bottles, 114 F.Supp. 461.

39. 21 C.F.R. § 1309.01; 21 C.F.R. § 1310.01
40. Illegal ephedrine abuse results from the overdosage of single-ingredient ephedrine products as well as from the diversion of ephedrine to substance production laboratories that modify ephedrine's chemical composition to produce methacatinone (CAT), an illicit substance. The proposed distribution controls on single-ingredient ephedrine would reduce ephedrine abuse due to diversion.
41. 21 C.F.R. § 1310.02; 21 C.F.R. § 1310.14; 21 C.F.R. § 1310.15
42. 21 C.F.R. § 1310.14; 21 C.F.R. § 1310.15
43. 21 C.F.R. § 1309.21; 21 C.F.R. § 1309.22
44. 21 C.F.R. § 1309.71 (a)(2)
45. 21 C.F.R. § 1310.05 (a)(1)
46. e.g., Pfizer, Inc., 81 F.T.C. 23 (1972) (requiring "reasonable basis" for affirmative drug product claims).

47. e.g., 21 C.F.R. § 201.302 (warning requirement against administration of mineral oil to infants); 21 C.F.R. § 201.303 (warning requirement against misuse of products containing wintergreen oil); 21 C.F.R. § 201.319 (warning requirement for water-soluble gums); 21 C.F.R. § 201.314 (Reye syndrome warning adopted in lieu of removing products from the market).

Promotional Materials

INSTANT ENERGY

BRONCHODILATOR

EPHEDRINE PRODUCTS

	100CT	250CT	500CT
301 Mini Pink Hearts 25mg. HCL	\$6.00	\$11.00	\$15.00
302 Mini White Thins 25mg. HCL	\$6.00	\$10.00	\$12.00
303 Maxi White Tabs 25mg. HCL	\$6.00	\$11.00	\$15.00
304 Mini White Tabs 25mg. Sulf	\$6.00	\$11.00	\$15.00
305 Yellow Caps 25mg.	\$6.00	\$15.00	\$18.00

PSEUDOEPHEDRINE

310 Mini White Round HCL	\$7.00	\$14.00	\$17.00
311 White Pick Sticks 30mg. HCL	\$6.00	\$11.00	\$16.00

BRONCHODILATOR & EXPECTORANT

320 2-Way EPH & Guaifenesin 25mg. HCL	\$7.00	\$14.00	\$17.00

ENERGY TABS & CAPSULES

CAFFEINE PRODUCTS

401 Pink Heart Tabs 200mg.	\$6.00	\$13.00	\$20.00
402 357 Magnum Tabs 200mg.	\$6.00	\$13.00	\$20.00
403 Black Mole Caps 200mg.	\$7.00	\$15.00	\$22.00
404 Blue Clear Caps 200mg.	\$7.00	\$15.00	\$22.00
406 20/20 Tabs 175mg.	\$6.00	\$13.00	\$20.00
407 30/30 Tabs 175mg.	\$6.00	\$13.00	\$20.00
408 Speckled Tabs 150mg.	\$6.00	\$13.00	\$20.00

DIET AIDS


501 Red Clear Caps 75mg. PPA	\$7.00	\$15.00	\$22.00
503 Pink Cross Tabs 75mg. PPA	\$7.00	\$15.00	\$22.00

SLEEP AIDS

602 Green Caps 50mg. DPH	\$8.00	\$17.00	
603 Blue Tablets 50mg. DPH	\$8.00	\$15.00	

HERBS & VITAMINS

701 Golden Seal Root	\$12.00		
702 Herbal Blend	\$8.00		
703 Ma Huang	\$8.00		
704 Mega Vites	\$9.00		




SAVE 50%

Order Two Bottles By Phone or Mail and Receive 50% OFF the Second Bottle of Equal or Lesser Value Excluding Skin Care Products

COMPARE OUR PRICES!

HOW TO ORDER:

1. Call TOLL-FREE and order. We ship daily and you pay upon delivery.
2. Take advantage of our quality SAVINGS and send your money order with coupon.
3. Call TOLL-FREE and place your order on VISA or MasterCard.



OLYMPUS [®]

DISTRIBUTING COMPANY

P. O. BOX 1847 Council Bluffs, IOWA 51502

NAME _____

ADDRESS _____

CITY/STATE/ZIP _____



TELE. # _____ AGE _____

☐ Money Order ☐ VISA ☐ MasterCard Exp: Month Year

Credit Card No.

Signature _____

QTY	CODE	BOTTLE CT	PRODUCT NAME	PRICE

POSTAGE & HANDLING (PREPAID) \$3.00

AMOUNT ENCLOSED

THANK YOU!

OLYMPUS DISTRIBUTING COMPANY

CAUTION: INDIVIDUALS UNDER MEDICAL CARE SHOULD CONSULT THEIR PHYSICIANS
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CALL TOLL FREE **1-800-321-0383** OR ORDER BY MAIL

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NATURAL STEROL COMPLEX

This is the most balanced body-building supplement you can take while building perfectly defined muscle mass and density. Its nine-way formula combines natural sterols, glandulars, fat burners plus more into a time-released tablet - so it's working out even while you're not.



TESTORA


Derived from African tree bark and powered with Ginseng, this is the most concentrated anabolic formula of its kind.

#63 90 Tablets \$19.95

#126 120 Capsules \$39.95

CAUTION: Enhanced potency and physical stimulation has been regulated to occur with this product.

"Stero-Max is my competitive edge."
Casey Kucharyk
IFBB Champion



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ON THE GO
Flood your body and mind with pure natural energy. No stimulant comes close!

#36 90 tabs \$9.98
#94 120 tabs \$12.95

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Pharmaceuticals & Nutritionals

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TIRED...LISTLESS...RUNDOWN...
DRAGGED OUT? DISCOVER THE CURE
TO THOSE NO-ENERGY BLAHS!

#22	#28	#33	#34
357 Magnum	D&E 290	D&E 200	D&E 25-25
200 mg	200 mg	200 mg	110 mg
100	100	100	100
\$8.95	\$8.95	\$7.95	\$6.95
200	200	200	200
\$15.50	\$15.50	\$13.95	\$12.95
1000	1000	1000	1000
\$36.95	\$36.95	\$26.00	\$22.95

EPHEDRINE BRONCHODILATORS

CT.	TABS	CAPS	TABS
	#35	#ES25	#EP
100	\$7.95	\$7.95	\$7.95
200	\$14.95	\$15.25	\$14.95
1000	\$24.95	\$29.95	\$24.95

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3. Send Payment in Full



NJ Residents Add 5% Sales Tax. Add \$4.50 Shipping & Handling.

PENTHOUSE

00-0031

G282 GWBS G387 G357 GPKH GSMB GAWL GBLC GLGY GLGR GOWC GWCH
WHITE CROSS DECONGESTANTS

3 JARS OF 100 FOR \$10.00

---\$15.00 PER 500 • \$25.00 PER 1000

**CALL OR PHONE-IN
YOUR ORDER TODAY!
(PHONE ORDERS ARE C.O.D.)**

PHONE 1-419-698-4555 / 7 DAYS PER WEEK

MONEY ORDERS OR PERSONAL CHECKS ACCEPTED
FOR PRE-PAID ORDERS

TO ORDER BY MAIL, FILL OUT THIS FORM AND SEND TO:
GLOBAL DISTRIBUTING, P.O. BOX 7878, OREGON, OH 43616

NAME _____

ADDRESS _____ APT. # _____

CITY _____ STATE _____

PHONE _____ ZIP _____

DESCRIPTION CODE QTY. OF JARS UNIT COST TOTAL COST*

SHIPPING FOR PREPAID ORDERS \$3.00

TOTAL _____

PRODUCT	CODE	CA	ES	PP
CAPSULES				
MOLE	GMOL	200	-	-
LARGE BLACK	GLGB	200	-	-
LARGE YELLOW	GLGY	200	-	-
BLUE CLEAR	GBLC	200	-	-
SMALL BLACK	GSMB	125	-	-
TABLETS				
30-30	G303	200	-	-
357 MAGNUM	G357	200	-	-
20-20	G202	175	-	-
PINK HEARTS	GPKH	175	-	-
WHITE BLUE SPECKS	GWBS	150	-	-
*WHITE CROSS	GWCR	-	25	-
*WHITE CROSS THICK	GDWC	-	-	50

*Decongestants
Ephedrine Sulphate-ES Caffeine-CA
Phenylpropanolamine-PP

(Above Quantities
in Milligrams)

WHITE CROSS TABLETS (CODE GWCH) OR MINI
PINK HEARTS (CODE GMPH), EPHEDRINE
HYDROCHLORIDE 25 MG. 2 JARS OF 1,000 FOR
\$25 OR 3 JARS FOR \$30.

00-0032

T&M DELIVERS!

BUY 2 GET 1 FREE*

ENERGY TABS & CAPS (TO RESTORE MENTAL ALERTNESS)

	CAFFEINE	100 CT	250 CT	500 CT	2 LOTS OF 500 *
4. 357 MAGNUM TAB	200 mg	\$7.00	\$16.00	\$24.00	\$34.00
22. 357 MAGNUM CAP	200 mg	8.00	16.00	24.00	34.00
14. LARGE PINK HEART	200 mg	7.00	14.00	22.00	24.00
2. 30/30 TAB	175 mg	7.00	14.00	23.00	29.00
15. BLACK MOLE CAP	175 mg	8.00	16.00	24.00	34.00
17. WHITE MOLE CAP	150 mg	7.00	14.00	22.00	29.00
11. WHT/BLUE SPEC TAB	150 mg	7.00	14.00	22.00	29.00
3. 20/20 TAB	125 mg	7.00	14.00	22.00	29.00

DIET AIDS PHENYLPROPANOLAMINE (TO CURB THE APPETITE)

	PPA HCL	100 CT	250 CT	500 CT	2 LOTS OF 500 *
18. RED/CLEAR CAPSULE	75 mg	\$8.00	\$16.00	\$25.00	\$35.00
20. 36-24-36 TM CAPSULE	75 mg	8.00	16.00	25.00	35.00
21. 36-24-36 TM CAPLET	75 mg	8.00	16.00	25.00	35.00

BRONCHODILATOR (FOR THE TEMPORARY RELIEF OF PAROXYSMS OF ASTHMA)

	EPHEDRINE HCL	100 CT	250 CT	500 CT	2 LOTS OF 500 *
1. MINI PINK HEART	25 mg	\$7.50	\$14.50	\$17.50	\$25.00
5. THIN OR THICK	25 mg	7.50	14.50	17.50	18.00
19. EPHEO 25 CAP	25 mg	8.00	15.00	17.50	25.00

ALSO AVAILABLE DIPHENHYDRAMINE

	100 CT	500 CT
10. SLEEP AID	50 mg \$8.50	\$25.00

T&M DIST DEPT. 41, P.O. Box 228, COUNCIL BLUFFS, IA 51502

CAUTION: INDIVIDUALS UNDER MEDICAL CARE SHOULD CONSULT THEIR PHYSICIAN

NO SALES TO MINORS.

* THIS COMBINATION IS NOT INCLUDED IN THE "BUY 2 GET 1 FREE" OFFER.

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IN IOWA (712) 323-0639

HOW TO ORDER:

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2. Take advantage of our Quantity Savings and send your money order with coupon below.

TO: T&M DIST., DEPT. 41 P.O. Box 228, Council Bluffs, IA 51502

BUY 2 GET 1 FREE*

Send your money order (no personal checks)

TO: T&M DIST., DEPT. 41 P.O. Box 228, Council Bluffs, IA 51502

Name	QUANTITY	NAME OF PRODUCT	PRICE
Address			
City			
State			
Zip		POSTAGE & HANDLING	\$2.90
Age		AMOUNT ENCLOSED	

00-0033

3 JARS OF 100 FOR \$10.00 \$15.00 PER 500 • \$25.00 PER 1000																																		
CALL OR PHONE IN YOUR ORDER TODAY! (PHONE ORDERS ARE GOOD)																																		
PHONE 419-698-4555 / 7 DAYS PER WEEK MONEY ORDERS OR PERSONAL CHECKS ACCEPTED CASH PAID ORDERS																																		
ORDER BY MAIL: FILL OUT THIS FORM AND SEND TO: GLOBAL DISTRIBUTING CO. BOX 7878 OREGON, OH 43616																																		
NAME _____ ADDRESS _____ APT. # _____ CITY _____ STATE _____ PHONE _____ ZIP _____																																		
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>DESCRIPTION</th> <th>CODE</th> <th>QTY OF JARS</th> <th>UNIT COST</th> <th>TOTAL COST</th> </tr> </thead> <tbody> <tr><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr> <td colspan="3" style="text-align: right;">SHIPPING FOR PREPAID ORDERS</td> <td> </td> <td>\$3.00</td> </tr> <tr> <td colspan="3" style="text-align: right;">TOTAL</td> <td> </td> <td> </td> </tr> </tbody> </table>					DESCRIPTION	CODE	QTY OF JARS	UNIT COST	TOTAL COST																SHIPPING FOR PREPAID ORDERS				\$3.00	TOTAL				
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PRODUCT	CODE	CA	ES	PP
CAPSULES				
MOLE	GMOL	200	-	-
LARGE BLACK	GLGB	200	-	-
LARGE YELLOW	GLGY	200	-	-
BLUE CLEAR	GBLC	200	-	-
SMALL BLACK	GSMB	125	-	-
TABLETS				
30-30	G303	200	-	-
357 MAGNUM	G357	200	-	-
20-20	G202	175	-	-
PINK HEARTS	GPKH	175	-	-
WHITE BLUE SPECKS	GWBS	150	-	-
*WHITE CROSS	GWCR	-	25	-
*WHITE CROSS THICK	GDWC	-	-	50

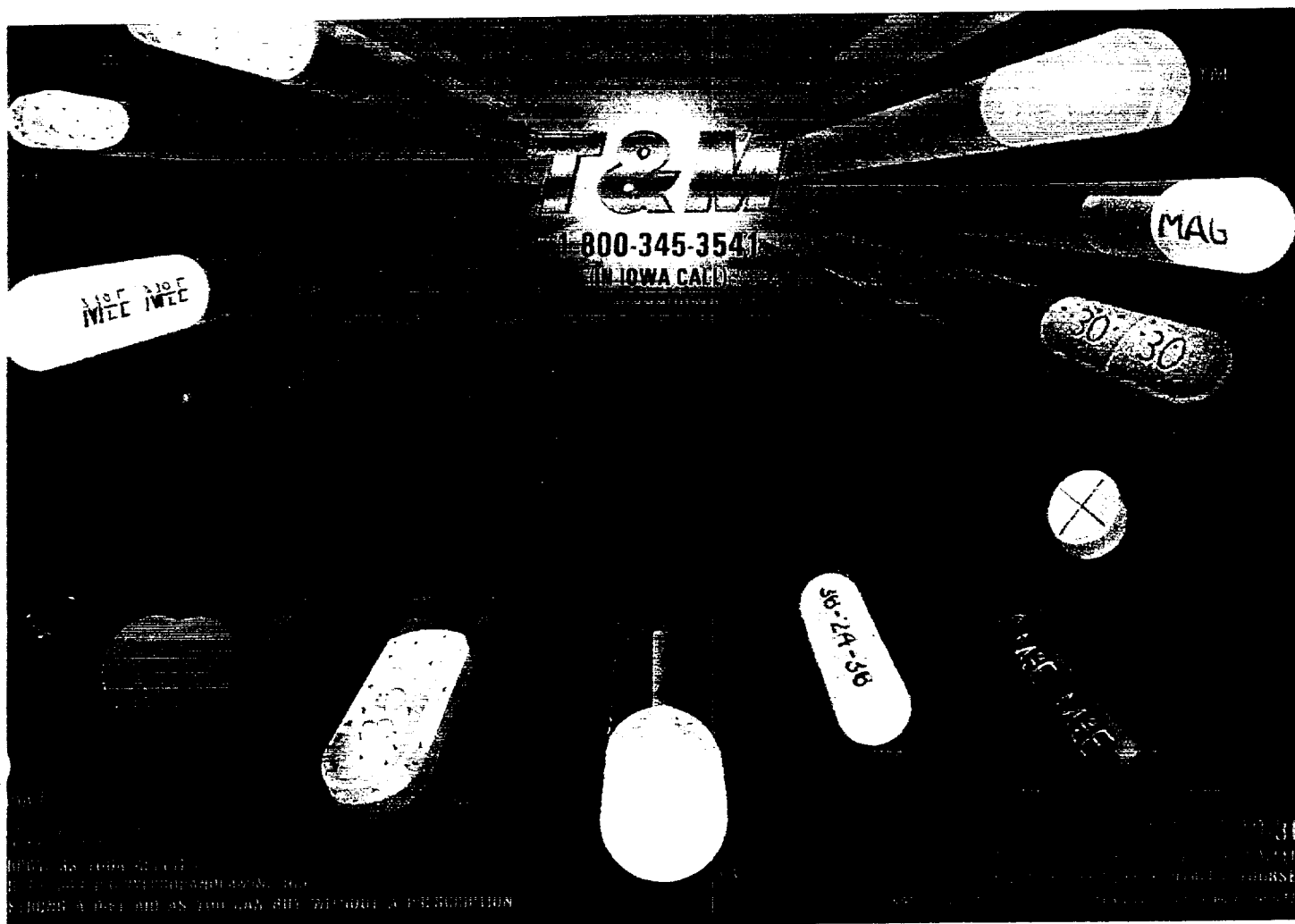
*Decongestants
 Ephedrine Sulphate-ES Caffiene-CA
 Phenylpropanolamine-PP

(Above Quantities in Milligrams)

WHITE CROSS TABLETS (CODE GWCH) OR MINI
 PINK HEARTS (CODE GMPH), EPHEDRINE
 HYDROCHLORIDE 25 MG. 2 JARS OF 1,000 FOR
 \$25 OR 3 JARS FOR \$30.

138 EXERCISE FOR MEN ONLY

00-0034



ENERGY TABS & CAPS (TO RESTORE MENTAL ALERTNESS)

	CAFFEINE	100 CT	250 CT	500 CT	2 LOTS OF 500 *
4. 357 MAGNUM TAB	200 mg	\$7.00	\$16.00	\$24.00	\$34.00
22. 357 MAGNUM CAP	200 mg	8.00	16.00	24.00	34.00
14. LARGE PINK HEART	200 mg	7.00	14.00	22.00	24.00
2. 30/30 TAB	175 mg	7.00	14.00	23.00	29.00
15. BLACK MOLE CAP	175 mg	8.00	16.00	24.00	34.00
17. WHITE MOLE CAP	150 mg	7.00	14.00	22.00	29.00
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3. 20/20 TAB	125 mg	7.00	14.00	22.00	29.00

DIET AIDS PHENYLPROPANOLAMINE (TO CURB THE APPETITE)

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18. RED/CLEAR CAPSULE	75 mg	\$8.00	\$16.00	\$25.00	\$35.00
20. 36-24-36 TM CAPSULE	75 mg	8.00	16.00	25.00	35.00
21. 36-24-36 TM CAPLET	75 mg	8.00	16.00	25.00	35.00

BRONCHODILATOR (FOR THE TEMPORARY RELIEF OF PAROXYSMS OF ASTHMA)

	EPHEDRINE HCL	100 CT	250 CT	500 CT	2 LOTS OF 500 *
1. MINI PINK HEART	25 mg	\$7.50	\$14.50	\$17.50	\$25.00
5. THIN OR THICK	25 mg	7.50	14.50	17.50	18.00
19. RATED 25 CAP	25 mg	8.00	15.00	17.50	25.00

ALSO AVAILABLE

DIPHENYDRAMINE

10. SLEEP AID	50 mg	\$8.50	N/A	\$25.00	N/A
---------------	-------	--------	-----	---------	-----

CAUTION: INDIVIDUALS UNDER MEDICAL CARE SHOULD CONSULT THEIR PHYSICIAN. NO SALES TO MINORS.
*THIS COMBINATION IS NOT INCLUDED IN THE "BUY 2 GET 1 FREE" OFFER. SAFE TAMPER RESISTANT PACKAGE.

HOW TO ORDER

1. Call toll free and order C.O.D. We ship daily and you pay upon delivery.
2. Take advantage of our Quantity Savings and send your money order with the coupon below to:

T&M DIST DEPT. 15

P.O. BOX 228, COUNCIL BLUFFS, IA 51502

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BUY 2 GET 1 FREE*

Send your money order to Dept. 15

T&M DIST., P.O. BOX 228, COUNCIL BLUFFS, IA 51502 • No Personal Checks

NAME _____ AGE _____

ADDRESS _____

CITY/ST/ZIP _____

QUANTITY	NAME OF PRODUCT	PRICE
	POSTAGE & HANDLING	\$2.90
	AMOUNT ENCLOSED	

00-0035

A Partnership in Profit.

When it comes to distributor support, no one can match PDK Labs for performance and profits.

The alertness aids category is booming and PDK Labs has the leading brands and programs to energize your business.



MaxAlert alertness aids and HerbAlert, our new all natural energy supplement, offer the highest dollar margins and super fast turns. Higher profit per square inch than candy,

cigarettes, chewing gum or any other category. And our products are thoroughly tested and quality-guaranteed to be 100% safe and effective.

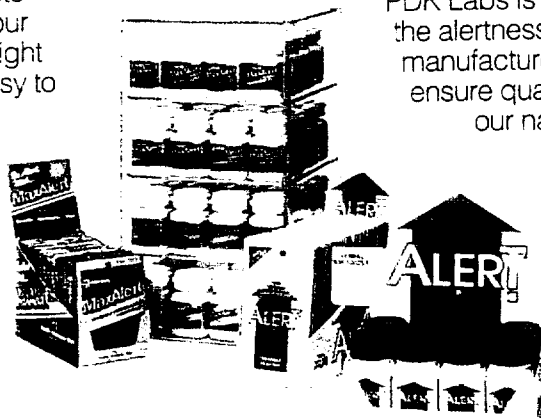
Merchandising and sales aids that pack in the profits.

PDK Labs markets its products with you in mind. That's why our sales stimulating displays fit right on the countertop and are easy to inventory and restock. No breakage. No spoilage. No returns... just repeat profits

Plus our free sampling program gives you a jump-start on profitable new business.

Advertising and publicity that pre-sell for you.

Our advertising, promotional support and publicity programs keep selling for you all year long...



generating leads, building awareness and stimulating new business.

Hardworking, full page four color ads and an extensive publicity campaign in national trade publications are going to help put your sales and profits over the top.



Profit from our energy.

PDK Labs is the leading manufacturer in the alertness aids category. As the prime manufacturer of all our products, we ensure quality from start to finish. We put our name and reputation on every product. And, we look to build your business with new, high-quality products and innovative merchandising and support that help you succeed.

Profit from our energy. Call 800-234-2000 today for more information on our distributor program.

**PDK
LABS INC.**

Profit from our energy
145 Ricefield Lane,
Hauppauge, NY 11788



Convenience Store News



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00-0036

STIMULATE YOUR OWN ECONOMY.

If the recession's got you down, PDK Labs has a complete line of alertness aids that will give your business a boost. MaxAlert® and HerbAlert®, our new all natural energy supplement, give you wholesale profit margins that can kick-start any economy. With alertness aids from PDK Labs, you're getting more than quality products from the industry's most established manufacturer. You're also getting a distributor merchandising program that includes in-store promotional material, as well as trade advertising to c-store owners. So start your economic recovery today. For more information, call PDK Labs at 1-800-234-2000.



PDK
LABS INC.

Profit from our energy

00-0037

ATTACHMENT 2
Summary of Nielsen Procision Sales Data

00-0042

Primatne Unit & Dollar Sales 1994-1997				
Total US All Outlets Combined				
	Full Year 94	Full Year 95	Full Year 96	Full Year 97
BRONCHIAL REMEDIES				
Unit Sales	9,560,969	9,378,213	8,905,269	9,012,610
Unit % Chg vs. YAG	2.1%	-1.9%	-5.0%	1.2%
Dollar Sales	\$84,633,638	\$83,925,597	\$81,401,760	\$84,440,287
\$ % Chg. vs. YAG	2.9%	-0.8%	-3.0%	3.7%
PRIMATENE MIST COMPLETE .50Z				
Unit Sales	1,561,841	1,599,109	1,721,506	1,719,885
Unit % Chg vs. YAG	-7.3%	2.4%	7.7%	-0.09%
Dollar Sales	\$17,891,579	\$18,287,116	\$19,979,570	\$20,477,056
\$ % Chg. vs. YAG	-3.8%	2.2%	9.3%	2.5%
PRIMATENE MIST REFILL .50Z				
Unit Sales	1,546,175	1,486,056	1,513,139	1,602,629
Unit % Chg vs. YAG	-14.4%	-3.9%	1.8%	5.9%
Dollar Sales	\$15,845,760	\$15,227,651	\$15,704,224	\$16,965,937
\$ % Chg. vs. YAG	-11.1%	-3.9%	3.1%	8.0%
PRIMATENE MIST REFILL .750Z				
Unit Sales	436,691	393,090	416,957	399,263
Unit % Chg vs. YAG	-3.9%	-10.0%	6.1%	-4.2%
Dollar Sales	\$6,101,534	\$5,486,242	\$5,809,289	\$5,688,022
\$ % Chg. vs. YAG	-1.8%	-10.1%	5.9%	-2.1%
PRIMATENE TAB 24 CT				
Unit Sales by Tablet	38,472,264	34,450,368	26,498,856	26,305,392
Unit Sales	1,603,011	1,435,432	1,104,119	1,096,058
Unit % Chg vs. YAG	-1.4%	-10.5%	-23.1%	-0.7%
Dollar Sales	\$8,425,958	\$7,651,058	\$5,828,111	\$5,745,294
\$ % Chg. vs. YAG	3.3%	-9.2%	-23.8%	-1.4%
PRIMATENE TAB 60 CT				
Unit Sales by Tablet	29,813,220	30,859,140	33,789,660	34,770,480
Unit Sales	496,887	514,319	563,161	579,508
Unit % Chg vs. YAG	-14.3%	3.5%	9.5%	2.9%
Dollar Sales	\$5,032,503	\$5,282,126	\$5,394,400	\$5,470,606
\$ % Chg. vs. YAG	-8.8%	5.0%	2.1%	1.4%
BRONKAID CAPLET 24 CT				
Unit Sales by Tablet		10,892,256	12,418,584	13,468,368
Unit Sales		453,844	517,441	561,182
Unit % Chg vs. YAG		N/A	14.0%	8.5%
Dollar Sales		\$2,394,506	\$2,795,405	\$3,043,280
\$ % Chg. vs. YAG		N/A	16.7%	8.9%
BRONKAID CAPLET 60 CT				
Unit Sales by Tablet		7,605,660	10,257,240	11,618,520
Unit Sales		126,761	170,954	193,642
Unit % Chg vs. YAG		N/A	34.9%	13.3%
Dollar Sales		\$1,236,205	\$1,704,432	\$1,961,044
\$ % Chg. vs. YAG		N/A	37.9%	15.1%
BRONKAID MIST COMPLETE .50Z				
Unit Sales		367,969	302,015	336,865
Unit % Chg vs. YAG		N/A	-17.9%	11.5%
Dollar Sales		\$4,077,788	\$3,474,773	\$3,899,319
\$ % Chg. vs. YAG		N/A	-14.8%	12.2%
BRONKAID MIST REFILL .50Z				
Unit Sales		307,029	258,448	282,885
Unit % Chg vs. YAG		N/A	-15.8%	9.5%
Dollar Sales		\$3,021,297	\$2,608,584	\$2,888,675
\$ % Chg. vs. YAG		N/A	-13.7%	10.7%
BRONKAID MIST REFILL .750Z				
Unit Sales		7,984	228	0
Unit % Chg vs. YAG		N/A	-97.1%	0.0%
Dollar Sales		\$103,750	\$3,148	\$0
\$ % Chg. vs. YAG		N/A	-97.0%	0.0%

Bronchial Remedies Brand Summary

Annual 1997				
	TOTAL US - ALL	TOTAL US -	TOTAL US - DRUG	TOTAL US - MASS
	OUTLETS COMBINED	FOOD/DRUG COMBOS	STORES OVER \$1MM	MERCHANDISER
PRIMATENE TAB 12 CT				
\$ Sales	\$312,702	\$138,732	\$173,975	\$0
U Sales	106,957	49,760	57,198	0
PRIMATENE TAB 24 CT				
\$ Sales	\$5,745,294	\$2,271,280	\$2,092,699	\$1,381,315
U Sales	1,096,058	451,346	363,431	281,278
PRIMATENE TAB 60 CT				
\$ Sales	\$5,470,606	\$667,049	\$2,980,952	\$1,822,608
U Sales	579,508	72,106	296,627	210,773
PRIMATENE DUAL ACTION TAB 24 CT				
\$ Sales	\$30,394	\$5,109	\$22,938	\$2,348
U Sales	5,658	1,046	4,128	485
PRIMATENE DUAL ACTION TAB 60 CT				
\$ Sales	\$8,586	\$5,563	\$2,755	\$269
U Sales	1,013	620	334	59
PRIMATENE M TAB 24 CT				
\$ Sales	\$0	\$0	\$0	\$0
U Sales	0	0	0	0
PRIMATENE M TAB 60 CT				
\$ Sales	\$0	\$0	\$0	\$0
U Sales	0	0	0	0
PRIMATENE P TAB 24 CT				
\$ Sales	\$0	\$0	\$0	\$0
U Sales	0	0	0	0
PRIMATENE P TAB 60 CT				
\$ Sales	\$0	\$0	\$0	\$0
U Sales	0	0	0	0
MINI THIN TAB BRONCHILATOR 36 CT				
\$ Sales	\$39	\$39	\$0	\$0
U Sales	13	13	0	0
TEDRAL TAB ASTHMA 100 CT				
\$ Sales	\$514	\$0	\$514	\$0
U Sales	26	0	26	0
THEODRINE TAB 100 CT				
\$ Sales	\$255	\$10	\$245	\$0
U Sales	17	1	16	0
BRONKAID CAPLET 24 CT				
\$ Sales	\$3,043,280	\$1,024,350	\$2,015,054	\$3,879
U Sales	561,182	202,252	358,025	904
BRONKAID CAPLET 60 CT				
\$ Sales	\$1,961,044	\$52,676	\$1,899,273	\$9,098
U Sales	193,642	5,527	187,102	1,011
NATURALIFE BRONCARE CAP ASTHMA 20 CT				
\$ Sales	\$892	\$892	\$0	\$0
U Sales	141	141	0	0
NATURALIFE CAP ASTHMA 100 CT				
\$ Sales	\$4,372	\$308	\$4,064	\$0
U Sales	557	33	524	0
NTRS HRBS BRONC-EASE CAP 50 CT				
\$ Sales	\$5,146	\$5,146	\$0	\$0
U Sales	473	473	0	0
NTRS HRBS BRONC-EASE CAP 60 CT				
\$ Sales	\$28,769	\$16,665	\$12,103	\$0
U Sales	3,479	2,020	1,460	0
NTRS HRBS BRONC-EASE PLUS CAP 20 CT				
\$ Sales	\$526	\$526	\$0	\$0
U Sales	98	98	0	0
NATURE'S WAY BREATH AID CAP 100 CT				
\$ Sales	\$12,242	\$12,242	\$0	\$0
U Sales	1,585	1,585	0	0
BOLT ENERGY TAB ASTHMA 105 CT				
\$ Sales	\$0	\$0	\$0	\$0
U Sales	0	0	0	0

00-0044

Bronchial Remedies Brand Summary

Annual 1996	TOTAL US - ALL OUTLETS COMBINED	TOTAL US - FOOD STORES OVER \$2MM	TOTAL US - FOOD/DRUG COMBOS	TOTAL US - DRUG STORES OVER \$1MM	TOTAL US - MASS MERCHANDISER
PRIMATENE TAB 12CT					
\$ SALES	\$576,648	\$138,982	\$67,192	\$370,024	\$450
U SALES	195,882	49,464	24,006	122,261	151
PRIMATENE TAB 24 CT					
\$ SALES	\$5,828,111	\$1,986,236	\$426,139	\$2,162,625	\$1,253,111
U SALES	1,104,119	389,509	81,847	375,807	256,956
PRIMATENE TAB 60 CT					
\$ SALES	\$5,394,400	\$297,650	\$333,407	\$3,161,742	\$1,601,601
U SALES	563,161	31,837	35,110	312,958	183,256
PRIMATENE DUAL ACTION TAB 24 CT					
\$ SALES	\$927,264	\$268,477	\$76,207	\$437,997	\$144,583
U SALES	176,017	51,857	14,691	79,878	29,591
PRIMATENE DUAL ACTION TAB 60 CT					
\$ SALES	\$405,993	\$22,707	\$24,794	\$338,103	\$20,389
U SALES	41,823	2,573	2,557	34,656	2,037
PRIMATENE M TAB 24 CT					
\$ SALES	\$2,521	\$0	\$0	\$2,521	\$0
U SALES	453	0	0	453	0
PRIMATENE M TAB 60 CT					
\$ SALES	\$11,379	\$0	\$0	\$11,379	\$0
U SALES	1,025	0	0	1,025	0
PRIMATENE P TAB 24 CT					
\$ SALES	\$500	\$0	\$0	\$500	\$0
U SALES	90	0	0	90	0
PRIMATENE P TAB 60 CT					
\$ SALES	\$2,753	\$0	\$0	\$2,753	\$0
U SALES	276	0	0	276	0
MINI THIN TAB ASTHMA 6 CT					
\$ SALES	\$0	\$0	\$0	\$0	\$0
U SALES	0	0	0	0	0
MINI THIN TAB BRONCHILATOR 100 CT					
\$ SALES	\$0	\$0	\$0	\$0	\$0
U SALES	0	0	0	0	0
MINI THIN TAB BRONCHILATOR 36 CT					
\$ SALES	\$21,854	\$21,308	\$546	\$0	\$0
U SALES	7,326	7,143	183	0	0
TEDRAL TAB ASTHMA 100 CT					
\$ SALES	\$0	\$0	\$0	\$0	\$0
U SALES	0	0	0	0	0
THEODRINE TAB 100 CT					
\$ SALES	\$19,548	\$0	\$331	\$11,461	\$7,756
U SALES	1,474	0	28	816	630
BRONKAID CAPLET 24 CT					
\$ SALES	\$2,796,109	\$585,293	\$324,564	\$1,882,590	\$3,662
U SALES	517,577	115,866	63,931	336,933	847
BRONKAID CAPLET 60 CT					
\$ SALES	\$1,704,486	\$32,412	\$31,758	\$1,630,639	\$9,677
U SALES	170,964	3,605	3,345	162,953	1,061
BRONCRIN CAP ASTHMA 20 CT					
\$ SALES	\$0	\$0	\$0	\$0	\$0
U SALES	0	0	0	0	0
NATURALIFE CAP ASTHMA 100 CT					
\$ SALES	\$15,980	\$1,903	\$921	\$13,156	\$0
U SALES	2,097	278	146	1,673	0
NATURALIFE BRONCARE CAP ASTHMA 20 CT					
\$ SALES	\$12,804	\$979	\$3,337	\$8,418	\$70
U SALES	1,929	165	513	1,216	35
NTRS HRBS BRONC-EASE CAP 50 CT					
\$ SALES	\$5,333	\$5,122	\$211	\$0	\$0
U SALES	478	456	22	0	0
NTRS HRBS BRONC-EASE CAP 60 CT					
\$ SALES	\$24,097	\$9,224	\$4,797	\$10,076	\$0
U SALES	2,892	1,107	583	1,202	0
NTRS HRBS BRONC-EASE PLUS CAP 20 CT					
\$ SALES	\$724	\$199	\$525	\$0	\$0
U SALES	139	36	103	0	0
NATURE'S WAY BREATH AID CAP 100 CT					
\$ SALES	\$1,294	\$715	\$579	\$0	\$0
U SALES	179	103	76	0	0
NATURE'S WAY HAS CAP 100 CT					
\$ SALES	\$0	\$0	\$0	\$0	\$0
U SALES	0	0	0	0	0

Bronchial Remedies Brand Summary

Annual 1995	TOTAL US - ALL OUTLETS COMBINED	TOTAL US - FOOD STORES OVER \$2MM	TOTAL US - FOOD/DRUG COMBOS	TOTAL US - DRUG STORES OVER \$1MM	TOTAL US - MASS MERCHANDISER
PRIMATENE TAB 24 CT					
\$ SALES	\$7,651,058	\$2,711,881	\$589,003	\$2,661,256	\$1,688,918
U SALES	1,435,432	518,046	112,769	456,102	348,515
PRIMATENE TAB 60 CT					
\$ SALES	\$5,282,126	\$394,278	\$408,879	\$3,748,792	\$730,177
U SALES	514,319	40,912	41,068	360,586	71,753
PRIMATENE DUAL ACTION TAB 24 CT					
\$ SALES	\$2,831,819	\$661,631	\$226,499	\$1,159,664	\$784,025
U SALES	535,674	127,163	44,195	204,453	159,863
PRIMATENE DUAL ACTION TAB 60 CT					
\$ SALES	\$983,094	\$51,841	\$53,286	\$626,026	\$251,941
U SALES	98,279	5,423	5,537	62,233	25,086
PRIMATENE M TAB 24 CT					
\$ SALES	\$5,056	\$0	\$0	\$5,056	\$0
U SALES	926	0	0	926	0
PRIMATENE M TAB 60 CT					
\$ SALES	\$35,255	\$0	\$0	\$35,255	\$0
U SALES	3,178	0	0	3,178	0
PRIMATENE P TAB 24 CT					
\$ SALES	\$4,313	\$0	\$0	\$4,313	\$0
U SALES	771	0	0	771	0
PRIMATENE P TAB 60 CT					
\$ SALES	\$7,519	\$0	\$0	\$7,519	\$0
U SALES	753	0	0	753	0
MINI THIN TAB ASTHMA 6 CT					
\$ SALES	\$174	\$174	\$0	\$0	\$0
U SALES	176	176	0	0	0
MINI THIN TAB BRONCHILATOR 100 CT					
\$ SALES	\$561	\$561	\$0	\$0	\$0
U SALES	\$188	\$188	\$0	\$0	\$0
MINI THIN TAB BRONCHILATOR 36 CT					
\$ SALES	\$15,866	\$14,294	\$1,572	\$0	\$0
U SALES	5,308	4,782	526	0	0
TEDRAL TAB ASTHMA 100 CT					
\$ SALES	\$0	\$0	\$0	\$0	\$0
U SALES	0	0	0	0	0
THEODRINE TAB 100 CT					
\$ SALES	\$79,629	\$70	\$314	\$37,212	\$42,033
U SALES	6,268	4	21	2,995	3,248
BRONKAID CAPLET 24 CT					
\$ SALES	\$2,394,506	\$466,817	\$292,972	\$1,625,075	\$9,642
U SALES	453,844	93,793	59,250	298,766	2,035
BRONKAID CAPLET 60 CT					
\$ SALES	\$1,236,205	\$32,297	\$27,299	\$1,169,143	\$7,466
U SALES	126,761	3,437	2,781	119,715	828
BRONCRIN CAP ASTHMA 20 CT					
\$ SALES	\$1,865	\$24	\$132	\$1,709	\$0
U SALES	321	4	24	293	0
NATURALIFE CAP ASTHMA 100 CT					
\$ SALES	\$55,116	\$3,219	\$2,087	\$49,326	\$484
U SALES	7,152	477	322	6,293	60
NATURALIFE BRONCARE CAP ASTHMA 20 CT					
\$ SALES	\$17,709	\$1,489	\$2,095	\$11,937	\$2,188
U SALES	2,936	247	340	1,858	491
NTRS HRBS BRONC-EASE CAP 50 CT					
\$ SALES	\$1,474	\$1,284	\$190	\$0	\$0
U SALES	133	115	18	0	0
NTRS HRBS BRONC-EASE CAP 60 CT					
\$ SALES	\$34,407	\$6,251	\$7,114	\$21,042	\$0
U SALES	4,243	771	865	2,607	0
NTRS HRBS BRONC-EASE PLUS CAP 20 CT					
\$ SALES	\$538	\$140	\$398	\$0	\$0
U SALES	110	29	81	0	0
NATURE'S WAY BREATH AID CAP 100 CT					
\$ SALES	\$1,534	\$1,049	\$485	\$0	\$0
U SALES	194	133	61	0	0
NATURE'S WAY HAS CAP 100 CT					
\$ SALES	\$0	\$0	\$0	\$0	\$0
U SALES	0	0	0	0	0

BRONCHIAL REMEDIES BRAND SUMMARY

1994					
	TOTAL US - ALL OUTLETS COMBINED	TOTAL US - FOOD STORES OVER \$2MM	TOTAL US - FOOD/DRUG COMBOS	TOTAL US - DRUG STORES OVER \$1MM	TOTAL US - MASS MERCHANDISER
PRIMATENE TAB 24 CT					
\$ Sales	\$8,431,557	\$2,972,542	\$691,121	\$3,057,812	\$1,710,082
U Sales	1,605,441	580,172	135,297	532,473	357,498
PRIMATENE TAB 60 CT					
\$ Sales	\$5,040,604	\$348,921	\$397,820	\$3,821,241	\$674,622
U Sales	498,271	38,640	40,965	351,100	88,588
PRIMATENE DUAL ACTION TAB 24 CT					
\$ Sales	\$2,839,210	\$783,596	\$237,584	\$1,137,162	\$700,878
U Sales	555,896	153,828	47,794	208,512	145,962
PRIMATENE DUAL ACTION TAB 60 CT					
\$ Sales	\$1,122,486	\$54,810	\$53,088	\$790,359	\$224,229
U Sales	117,865	6,013	5,728	82,105	23,818
PRIMATENE M TAB 24 CT					
\$ Sales	\$0	\$0	\$0	\$0	\$0
U Sales	0	0	0	0	0
PRIMATENE M TAB 60 CT					
\$ Sales	\$1,802	\$0	\$0	\$1,802	\$0
U Sales	195	0	0	195	0
PRIMATENE P TAB 24 CT					
\$ Sales	\$14,351	\$7,684	\$0	\$6,667	\$0
U Sales	2,621	1,374	0	1,247	0
PRIMATENE P TAB 60 CT					
\$ Sales	\$9,564	\$0	\$0	\$9,564	\$0
U Sales	957	0	0	957	0
AZMA-AID TAB 100 CT					
\$ Sales	\$0	\$0	\$0	\$0	\$0
U Sales	0	0	0	0	0
BRONITIN TAB ASTHMA 24 CT					
\$ Sales	\$0	\$0	\$0	\$0	\$0
U Sales	0	0	0	0	0
BRONITIN TAB ASTHMA 60 CT					
\$ Sales	\$102	\$102	\$0	\$0	\$0
U Sales	11	11	0	0	0
GENEVA GENERICS TAB ASTHMA 100 CT					
\$ Sales	\$0	\$0	\$0	\$0	\$0
U Sales	0	0	0	0	0
HEADS UP TAB ASTHMA 100 CT					
\$ Sales	\$0	\$0	\$0	\$0	\$0
U Sales	0	0	0	0	0
MINI THIN TAB ASTHMA 6 CT					
\$ Sales	\$209	\$209	\$0	\$0	\$0
U Sales	210	210	0	0	0
MINI THIN TAB BRONCHILATOR 100 CT					
\$ Sales	\$13,139	\$13,139	\$0	\$0	\$0
U Sales	3,455	3,455	0	0	0
TEDRAL TAB ASTHMA 24 CT					
\$ Sales	\$0	\$0	\$0	\$0	\$0
U Sales	0	0	0	0	0
TEDRAL TAB ASTHMA 100 CT					
\$ Sales	\$0	\$0	\$0	\$0	\$0
U Sales	0	0	0	0	0
THEODRINE TAB 100 CT					
\$ Sales	\$42,139	\$0	\$103	\$9,052	\$32,984
U Sales	4,080	0	13	1,040	3,007

SOURCE: NIELSEN PROCISION DATA

00-0047

BRONCHIAL REMEDIES BRAND SUMMARY

ANNUAL 1993					
	TOTAL US - ALL OUTLETS COMBINED	TOTAL US - FOOD STORES OVER \$2MM	TOTAL US - FOOD/DRUG COMBOS	TOTAL US - DRUG STORES OVER \$1MM	TOTAL US - MASS MERCHANDISER
PRIMATENE TAB 24 CT					
\$ Sales	\$8,177,031	\$2,958,555	\$672,315	\$2,964,033	\$1,582,128
U Sales	1,630,088	595,599	137,491	542,122	354,876
PRIMATENE TAB 60 CT					
\$ Sales	\$5,522,801	\$392,820	\$480,217	\$3,861,643	— \$788,121
U Sales	581,158	44,077	52,028	395,856	89,198
PRIMATENE DUAL ACTION TAB 24 CT					
\$ Sales	\$1,894,477	\$430,718	\$158,158	\$765,735	\$339,868
U Sales	342,837	89,871	32,754	144,321	75,891
PRIMATENE DUAL ACTION TAB 60 CT					
\$ Sales	\$679,390	\$22,101	\$26,220	\$543,238	\$87,831
U Sales	73,235	2,577	2,960	57,788	9,930
PRIMATENE M TAB 24 CT					
\$ Sales	\$25,316	\$27	\$20	\$25,298	\$0
U Sales	5,207	5	4	5,198	0
PRIMATENE M TAB 60 CT					
\$ Sales	\$6,877	\$0	\$0	\$6,877	\$0
U Sales	720	0	0	720	0
PRIMATENE P TAB 24 CT					
\$ Sales	\$56,831	\$315	\$0	\$56,516	\$0
U Sales	9,231	67	0	9,164	0
PRIMATENE P TAB 60 CT					
\$ Sales	\$39,466	\$0	\$0	\$39,466	\$0
U Sales	3,798	0	0	3,798	0
AZMA-AID TAB 100 CT					
\$ Sales	\$259	\$0	\$0	\$259	\$0
U Sales	59	0	0	59	0
BRONITIN TAB ASTHMA 24 CT					
\$ Sales	\$635	\$211	\$0	\$424	\$0
U Sales	127	42	0	65	0
BRONITIN TAB ASTHMA 60 CT					
\$ Sales	\$0	\$0	\$0	\$0	\$0
U Sales	0	0	0	0	0
GENEVA GENERICS TAB ASTHMA 100 CT					
\$ Sales	\$1,781	\$282	\$37	\$1,442	\$0
U Sales	488	71	12	385	0
HEADS UP TAB ASTHMA 100 CT					
\$ Sales	\$0	\$0	\$0	\$0	\$0
U Sales	0	0	0	0	0
MINI THIN TAB ASTHMA 8 CT					
\$ Sales	\$344	\$344	\$0	\$0	\$0
U Sales	348	348	0	0	0
MINI THIN TAB BRONCHILATOR 100 CT					
\$ Sales	\$14,054	\$14,054	\$0	\$0	\$0
U Sales	2,780	2,780	0	0	0
TEDRAL TAB ASTHMA 24 CT					
\$ Sales	\$8,807	\$212	\$2,802	\$3,583	\$0
U Sales	638	18	254	388	0
TEDRAL TAB ASTHMA 100 CT					
\$ Sales	\$0	\$0	\$0	\$0	\$0
U Sales	0	0	0	0	0
THEODRINE TAB 100 CT					
\$ Sales	\$20,818	\$68	\$78	\$4,971	\$15,503
U Sales	2,354	8	16	569	1,761

SOURCE: NIELSEN PROCISION DAT.

00-0048

BRONCHIAL REMEDIES BRAND SUMMARY

1992					
	TOTAL US - ALL OUTLETS COMBINED	TOTAL US - FOOD STORES OVER \$2MM	TOTAL US - FOOD/DRUG COMBOS	TOTAL US - DRUG STORES OVER \$1MM	TOTAL US - MASS MERCHANDISER
PRIMATENE TAB 24 CT					
\$ Sales	\$8,135,498	\$2,948,829	\$850,893	\$3,279,776	\$1,256,168
U Sales	1,648,018	604,586	136,138	619,062	288,232
PRIMATENE TAB 60 CT					
\$ Sales	\$5,355,311	\$297,067	\$426,614	\$3,855,251	\$778,379
U Sales	578,277	34,250	48,216	408,651	89,180
PRIMATENE DUAL ACTION TAB 24 CT					
\$ Sales	\$0	\$0	\$0	\$0	\$0
U Sales	0	0	0	0	0
PRIMATENE DUAL ACTION TAB 60 CT					
\$ Sales	\$0	\$0	\$0	\$0	\$0
U Sales	0	0	0	0	0
PRIMATENE M TAB 24 CT					
\$ Sales	\$71,350	\$2,026	\$98	\$69,226	\$0
U Sales	13,981	401	19	13,541	0
PRIMATENE M TAB 60 CT					
\$ Sales	\$88,227	\$2,838	\$248	\$85,141	\$0
U Sales	9,576	318	28	9,230	0
PRIMATENE P TAB 24 CT					
\$ Sales	\$31,401	\$11,581	\$81	\$19,779	\$0
U Sales	6,110	2,749	13	3,348	0
PRIMATENE P TAB 60 CT					
\$ Sales	\$11,135	\$1,100	\$157	\$9,878	\$0
U Sales	1,300	122	18	1,160	0
AZMA-AID TAB 100 CT					
\$ Sales	\$0	\$0	\$0	\$0	\$0
U Sales	0	0	0	0	0
BRONITIN TAB ASTHMA 24 CT					
\$ Sales	\$84,349	\$4,337	\$844	\$59,368	\$0
U Sales	13,249	925	140	12,164	0
BRONITIN TAB ASTHMA 60 CT					
\$ Sales	\$6,304	\$804	\$2,425	\$3,075	\$0
U Sales	653	90	278	285	0
GENEVA GENERICS TAB ASTHMA 100 CT					
\$ Sales	\$41,944	\$1,449	\$1,533	\$38,636	\$328
U Sales	11,923	374	607	10,869	73
HEADS UP TAB ASTHMA 100 CT					
\$ Sales	\$5,083	\$5,083	\$0	\$0	\$0
U Sales	848	848	0	0	0
MINI THIN TAB ASTHMA 6 CT					
\$ Sales	\$0	\$0	\$0	\$0	\$0
U Sales	0	0	0	0	0
MINI THIN TAB BRONCHILATOR 100 CT					
\$ Sales	\$7,764	\$7,764	\$0	\$0	\$0
U Sales	1,998	1,998	0	0	0
TEDRAL TAB ASTHMA 24 CT					
\$ Sales	\$85,083	\$4,036	\$13,387	\$67,640	\$0
U Sales	6,803	363	1,387	5,053	0
TEDRAL TAB ASTHMA 100 CT					
\$ Sales	\$42,300	\$235	\$7,938	\$34,127	\$0
U Sales	1,109	8	289	812	0
THEODURNE TAB 100 CT					
\$ Sales	\$50,383	\$299	\$0	\$18,929	\$33,155
U Sales	8,317	116	0	3,062	5,139

SOURCE: NIELSEN PROCISSION DATA

00-0049

ATTACHMENT 3

DAWN Data - Background and Methodology*

Dawn is a large-scale, ongoing drug abuse data collection system sponsored by SAMHSA. The major objectives of the system are:

- To identify substances associated with drug abuse episodes that are reported by DAWN-affiliated facilities;
- To monitor drug abuse patterns and trends and to detect new abuse entities and new combinations;
- To assess health hazards associated with drug abuse; and
- To provide data for national, state, and local drug abuse policy and program planning.

For the purposes of reporting to the DAWN system, drug abuse is defined as the nonmedical use of a substance for psychic effect, dependence, or suicide attempt/gesture. Nonmedical use includes:

- The use of prescription drugs in a manner inconsistent with accepted medical practice;
- The use of over-the-counter (O.T.C.) drugs contrary to approved labeling; or
- The use of any other substance (heroin, cocaine, marijuana, glue, aerosols, etc.) for psychic effect, dependence, or suicide.

*Taken from: Annual Emergency Room Data 1992: Data from the Drug Abuse Warning Network (DAWN); Series 1, Number 12-A. U.S. Department of Health and Human Services, Public Health Service, Substance Abuse and Mental Health Services Administration; pp. 5-6, March 1994.

ATTACHMENT 4

Methodology

National Family Opinion (NFO) Survey

NFO maintains a consumer panel representing 450,000 households. In 1992, NFO created their "Chronic Ailment Panel" which was updated in 1994 to include a total of 200,000 households representative of the U.S., which covers over 60 ailments including asthma. Specifically, panel members were surveyed by mail and asked which ailments individuals in the household suffer from, and whether or not those ailments are treated with prescription or nonprescription medication.

Telephone interviews were conducted in January 1995 among a representative sample of adult asthma sufferers identified in the Chronic Ailment Panel who reported use of nonprescription ephedrine combination (tablets) in the past year. Interviews were completed among a total of 210 past year users of this medication.

Respondents were asked about their use of non-prescription asthma medication (epinephrine or ephedrine combination) in the past year, their usage of prescription products and/or non-prescription epinephrine (mist) if ephedrine combination (tablets) were not available, use of prescription asthma medications, and usage patterns of ephedrine combination (tablets), including symptoms treated

and product satisfaction. Physician visitation and demographics were obtained at the end of the questionnaire.

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